

A Relationship Between Six Sigma and ISO 9000:2000

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We propose a strategy for the implementation of the Six Sigma method as an improvement solution for the ISO 9000:2000 Quality Standard. Our approach is focused on integrating the DMAIC cycle of the Six Sigma method with the PDCA process approach, highly recommended by the standard ISO 9000:2000. The Six Sigma steps applied to each part of the PDCA cycle are presented in detail, along with some tools and training examples.

Based on this analysis, the authors conclude that applying Six Sigma philosophy to the quality standard implementation process is the best way to achieve the optimal results in quality progress and therefore in customer satisfaction.

Keywords ISO 9000; PDCA; Six Sigma; DMAIC.

1. INTRODUCTION

The new version of the ISO 9000 standards came with new ideas in the company quality approach. It is already known that the process approach, continuous quality improvement, and customer focus are the major new specific demands required by ISO 9000:2000. These demands correspond perfectly to the philosophy of another very well-known quality focus method: the Six Sigma method.

This new idea means changes, and changes mean management involvement, people motivation, and training, but the most difficult challenge is making people think outside the box. Besides that, ISO 9000:2000 requires new measurement methods, even new quality improvement tools and higher leadership capacities. These require important human and financial resources. Then, a very important effort is required

when the company decides to improve the system, making in place a sophisticated and more performed method.

In this article, we focus on the Plan Do Check Act (PDCA) (invented by Shewhart, 1939, and developed by Deming, 1982, “the Deming wheel”) process approach, highly recommended by the ISO 9000:2000 standard because this is the first major change to be implemented in the company quality system, and we refer at the Six Sigma method (Harry and Schroeder, 2000) only from its management point of view. Showing that it is possible to apply the Six Sigma methodology on each element of the PDCA cycle, we hope to reveal new possibilities and ideas in using Six Sigma: we may apply Six Sigma philosophy in any process and integrate it with the existing quality system.

2. PROCESS APPROACH

The process approach (Figure 1) means that the company is a complex process with incoming specifications/demands from the customers and outgoing results (product/service) to the customers.

The advantages of this approach are revealed in the ISO quality standard (ISO 9000:2000):

- Measuring the performances and the process efficiency.
- Continuous process improvement based on realistic measures.
- Understanding and accomplishing the exigencies.

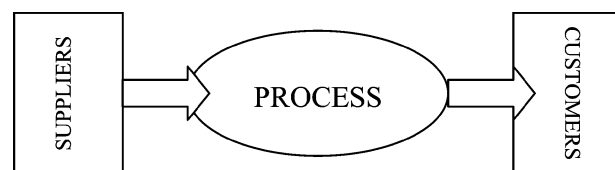


Figure 1. Process approach.

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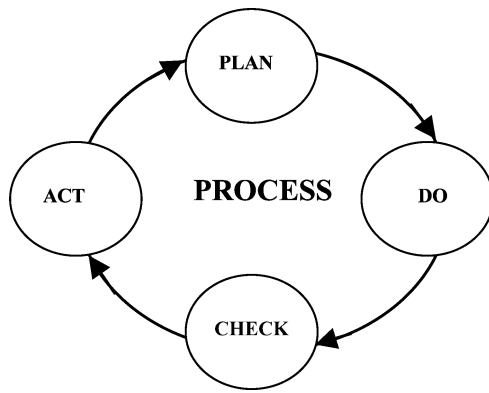


Figure 2. PDCA cycle.

The tool presented by the quality standard, as a model for the process approach, that covers every exigency of the standard is the PDCA cycle (Figure 2).

Plan: Establishing the objectives and the processes needed to meet all the customers requirements, being also conform to the company policy.

Do: Implementing the processes.

Check: Processes surveillance and measurements, conforming to policies, objectives, and product exigencies.

Act: Acting to continuously improve the process performances.

3. SIX SIGMA METHODOLOGY

Six Sigma means a measure of quality that strives for near perfection. Six Sigma is a disciplined, data-driven approach and methodology for eliminating defects (driving toward six standard deviations between the mean and the nearest specification limit) in any process: from manufacturing to transactional and from product to service (www.isixsigma.com).

The statistical representation of Six Sigma describes quantitatively how a process is performing. To achieve Six Sigma, a process must not produce more than 3.4 defects per 1 million opportunities. A Six Sigma defect is defined as anything outside customer specifications. A Six Sigma opportunity is the total quantity of chances for a defect. Six Sigma processes are executed by Six Sigma Green Belts and Six Sigma Black Belts, who are overseen by Six Sigma Master Black Belts.

The fundamental objective of the Six Sigma methodology is the implementation of a measurement-based strategy that focuses on process improvement and variation reduction. This is accomplished through the use of (Define, Measure, Analyze, Improve, Control) DMAIC cycle. The Six Sigma DMAIC process is an improvement system for existing processes falling below specification and looking for incremental improvement but also used to develop new processes or products at Six Sigma quality levels:

- **Define:** Define the relevant process and establish the customer needs.
- **Measure:** Process data are collected and special characteristics are categorized; establish if the changes (of the process improvement) are advantageous.
- **Analyze:** Convert and analyze the data; detects the most important causes of process unconformity.
- **Improve:** Develop solutions and implement changes to correct the problems.
- **Control:** The whole process is monitored.

4. ISO 9001 VERSUS SIX SIGMA

4.1. Six Sigma Filter

We saw that the goal of the Six Sigma method is to reduce the dispersion priority for those characteristics that are essential for the customer satisfaction: customer focused. Plus, it can be applied to each process. An idea of combining ISO and Six Sigma was developed par Patrick Dey and consist in integrating the DMAIC cycle as an interface (Filter) between the customers and the ISO quality system (Figure 3).

4.2. ISO Cartography and Six Sigma Method

Another approach is proposed by Kobi et al. (2002) and is based on the complementarities between ISO and Six Sigma. This approach suppose the implementation of ISO 9000 standard, meaning:

- Establish the cartography of the company.
- Identify and define all processes.
- For every process, identify the inputs and outputs.

After all of these have been done, we may apply the Six Sigma methodology on each processes to evaluate it after the Six Sigma metrics (Figure 4).

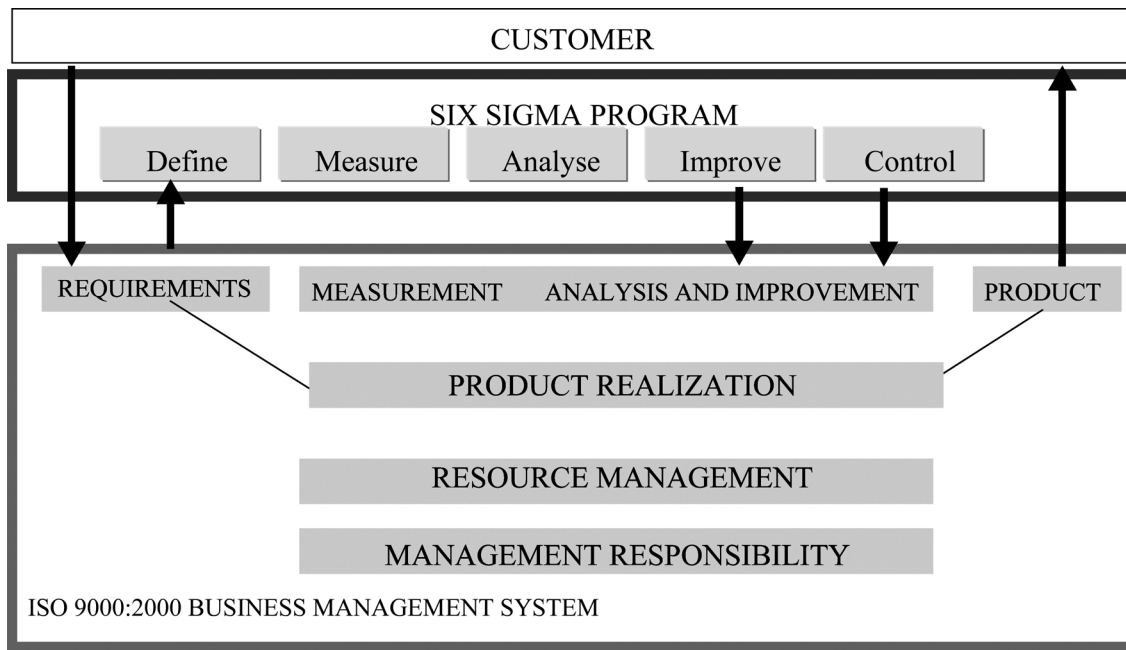


Figure 3. Six Sigma filter.

Depending on the human and material resources of the company, we can apply the Six Sigma method on all processes at the same time, or choose to implement it on each process at a time, but ordered function

of the importance of the processes on the final product or services.

An integrated Six Sigma and ISO 9001 Quality Management System is based on the following principles:

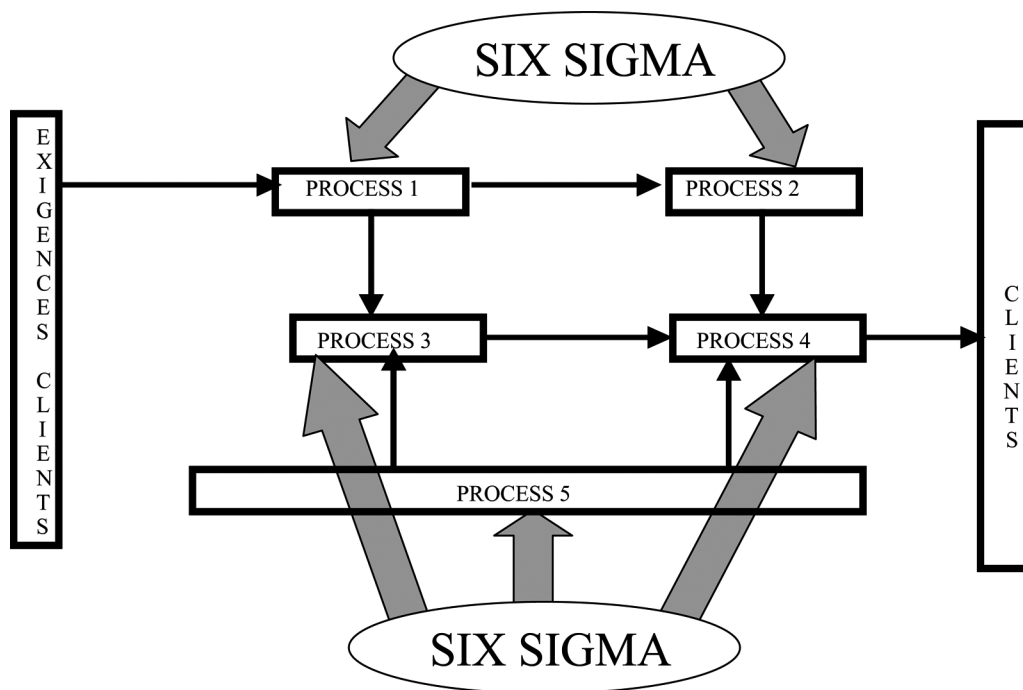


Figure 4. ISO cartography and Six Sigma method.

- The Six Sigma program becomes its own venue for project-related performance reviews, but it does not exist in a vacuum. It takes direction from senior management and interacts closely with the ISO 9001 management review process. That is, it reports on progress with regard to quality objectives and receives input and direction, including reviews of the overall Six Sigma program and recommendations on ways to continually improve the Six Sigma program itself, from the management review group.
- Six Sigma projects are targeted at all types of processes: operational, support, supplier, and customer. These projects become one of the methods through which actual continual improvement takes place; this is continual improvement in trenches.
- The existing ISO 9001 internal audit program has been expanded to include not only audits of the administrative features of the company's Six Sigma program, but also individual control phase and closed projects. This ensures a successful Six Sigma program and the viability of continual improvement activities related to Six Sigma projects.

5. DMAIC APPLIED ON THE PDCA CYCLE

Applying the Six Sigma methodology to the PDCA cycle, not only will improve the standard implementation, but also will improve the process. Studying Figure 5 we can observe that, in fact, we apply the Six Sigma method to each part of the process, not only to the entire process. Taking account of the fact that Six Sigma means only 3.4 defects per 1 million you will really improve the company activity.

Each step of the Six Sigma method requires specific tools. Usually the Black Belts, Six Sigma specialists, choose the best tool, taking account of the nature of the process. We saw that the process approach means that the company itself is a process that can be divided in subprocesses. For example, we can consider that a company contains the supplier process, the project process, the developing process, the delivery process, and so on.

Furthermore, we develop what it means to apply the Six Sigma steps to each part of the PDCA cycle, along with some tools and training examples.

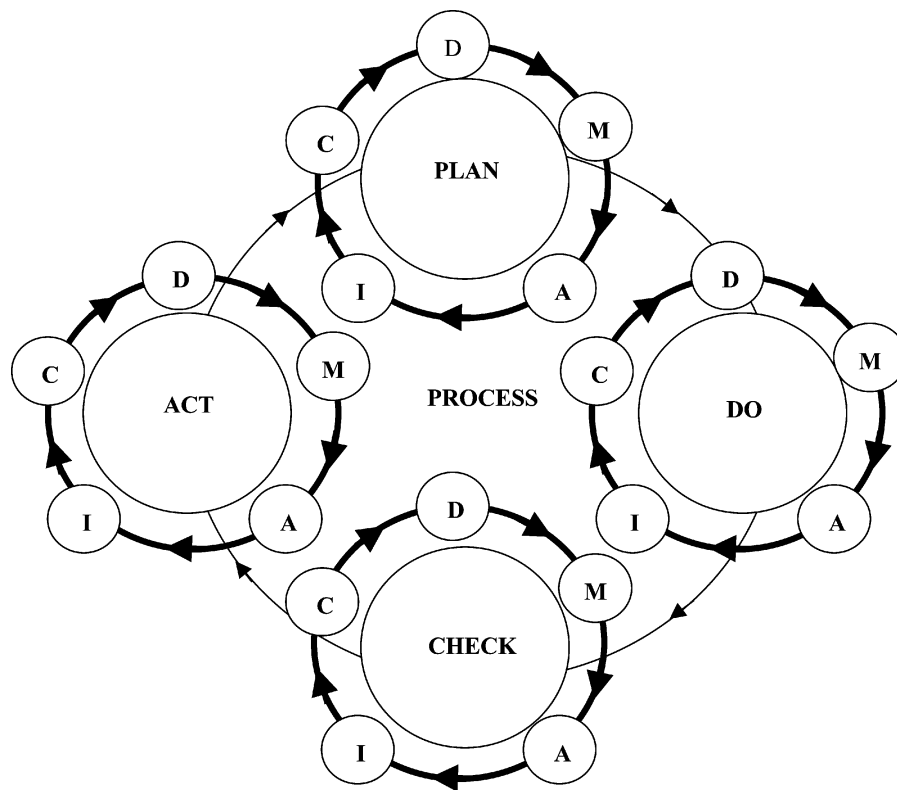


Figure 5. DMAIC applied on the PDCA cycle.

5.1. DMAIC Cycle for Plan

- **Define** the objectives, combining the quality standards demands with the “zero defaults” Six Sigma objective. Establishing why you choose to improve the quality system and why Six Sigma. How its objective and method will complete the company’s actual system.

It is important to begin training by explaining the context of Six Sigma, followed by an introductory to the DMAIC and Design for Six Sigma (DFSS) tools (Hoerl, 2001). Fundamentals for project management and team effectiveness are also considered.

- **Measure** the company Six Sigma level, gathering all the data from intern and extern (customers, suppliers).

The issue of data quality is very important. This is needed in addition to understanding the impact of sample size. The traditional Six Sigma measurement system analysis focuses on repeatability and reproducibility (R&R) studies (Automotive Industry Action Group, 1990).

- **Analyze** all the data. Establish how many improvement projects will be developed and how many Black Belts are needed.
- Establishing the **improvement** steps and tools conforming to the Six Sigma level.
- Establish the **control** procedures and responsible. Develop control plans and charts.

5.2. DMAIC Cycle for Do

- Correlate the customers needs with each department (process) of the company. **Define** priorities at the lowest possible level.

At this stage project selection tools, along with scooping project tools, are used to identify the relevant processes (SIPOC—process map identifying suppliers, inputs, process steps, outputs, and customers). Also at the define step of the doing process are tools used for multigenerational projects and for developing project plans.

- **Measure** each process distribution and capability. Establish the Six Sigma level for every process.

This level introduces the concept of process stability and implications of instability using run charts. As

tools for this level are developing measurable critical-to-quality (CTQ) metrics, quality function deployment (QFD) (Cohen, 1995), and statistical process control (SPC) techniques (Wheeler and Chambers, 1992): the concept of statistical control (process stability) and the implications of instability on capability measures. Also, capability analysis are a must.

- **Analyze** all the data for all the processes. Detect the most important causes for process variation. Choose the best method to lower the variation and upgrade the capability.

Graphical improvement tools are requested, such as Pareto chart, histograms, run charts, and scatter plot. This is the step when management and planning tools (like affinity diagram or interrelationship diagram) are to be used. Among other tools used in the analyze level of the do step, we present the analysis of variance (ANOVA) (Miller, 1997) and conceptual designs for Six Sigma (DFSS).

- The Black Belts will manage all the **improvement** processes, implementing changes in order to correct the problems.

This is the level where design of experiments tools are used (e.g., factorial experiments, fractional factorials, balanced block designs, and response surface design), along with failure mode and effects analysis (FMEA) (McDermott et al., 1996) and design for Six Sigma tools (CTQ flowdown, capability flowup, and simulation).

- Check the **control** charts and diagrams to verify the process improvement status. Compare the results with the expectations and indicate if is necessary to establish corrective actions.

5.3. DMAIC Cycle for Check

- **Define** clearly what were the objectives and what improvement processes have been implemented. Take account of the starting level for each process. Estimate process tools with control plans and control charts.
- **Measure** the progress at the company level and for each particular process.

Sampling tools are needed to measure the data quality and quantity.

- **Analyze** the improvement process and establish a correlation between the level reached and the performances expected.

This is the step where the confidence intervals are verified and the hypotheses are tested.

- Establish if changes are to be done or the **improvement** process will continue until now. Choose more reporting types to have new perspectives on the data.
- **Control** the checking process, all the data involved, and how the measurements were done.

5.4. DMAIC Cycle for Act

- **Define** what are the next steps to continually improve the quality. Establish the processes that need special attention.
- Take account of all quality indicators (**measure**), interview the customers about their satisfaction, and interview the employees about their working conditions.
- **Analyze** the evolution of the company quality system, measuring the customer's satisfaction, company Six Sigma level, and some other quality indicators.
- Choose more powerful **improvement** tools, train new employees, try to impose higher quality standards to suppliers, implement new indicators, and so on.

At this stage, we are piloting the DMAIC improvements.

- Monitor all decisions that were made and **control** whether they respond to the quality improvement process.

Typical to Six Sigma methodologies, the performance of the process at the start of the project is recorded in a run chart or a control chart. As the process progresses, further points are plotted. At the completion of the project, the improvement is clear. The charts are prominently displayed alongside others diagrams with a clear explanation of what is being measured and how we arrived at the chosen improvement action. Managers have been trained to expect and demand this style of reporting.

6. CONCLUSIONS

It is well known that the huge success and impressive business performances of big companies like

Motorola, General Electric, Allied Signal, Black and Decker are due to the implementation of the Six Sigma methods. Surprising is the fact that Six Sigma is based on ideas and tools that existed (Calcutt, 2001) (the reduction of process variation was advocated many years ago by Deming, 1993, and Taguchi, 1987).

An important feature of the Six Sigma culture is the existence of what could be described as management by fact. Once top management decides to implement an ISO quality system in the company, there are some obligatory changes that need to be done (e.g., process approach, customer focus, and continuous improvement). Because they have to develop new techniques to correspond to the standard demands, it is a very good approach to think about the Six Sigma implementation from the beginning.

Applying Six Sigma philosophy to the quality standard implementation process is the best way to achieve the optimal results in quality progress and therefore in customer satisfaction.

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